IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BARD PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION FILE NO.: 2:10-MD-2187**

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

VICKIE MCCLOSKEY	**2:14-cv-3784**
CHRISTINA PORTER	**2:13-cv-33321**
LINDA PRATER	**3:13-cv-14451**
LINDA RICHARDS	**2:13-cv-27937**

DEFENDANT C. R. BARD, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTIONS FOR PARTIAL SUMMARY JUDGMENT AS TO PLAINTIFFS WHOSE CLAIMS ARE GOVERNED BY INDIANA LAW

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Defendant C. R. Bard, Inc. ("Bard") hereby submits its memorandum of law in support of its motions for partial summary judgment in the above-captioned cases. In support of its motions, Bard shows the Court as follows.

INTRODUCTION

Plaintiffs Vickie McCloskey, Christina Porter, Linda Prater and Linda Richards (collectively, "Plaintiffs") all received pelvic mesh products manufactured by Bard and allege damages related to the devices they received. Plaintiffs are all Indiana residents who had a Bard Align product implanted in Indiana by an Indiana doctor:

- **Vickie McCloskey** was implanted with an Align to treat her SUI on December 29, 2009 by Dr. William Shirrell[1] at Naab Road Surgery Center in Indianapolis, Indiana;
- **Christina Porter** was implanted with an Align on February 24, 2009 by Dr. Rebecca Brewer[2] at Bloomington Hospital in Bloomington, Indiana;
- **Linda Prater** was implanted with an Align on March 10, 2010 by Dr. Romel Antolin[3] at Henry County Hospital in New Castle, Indiana; and
- **Linda Richards** was implanted with an Align on August 4, 2009 by Dr. Vernon Maes[4] at Goshen General Hospital in Goshen, Indiana.

Over the course of discovery, it has become increasingly clear that several of plaintiffs' legal theories are without evidentiary support and therefore are subject to dismissal as a matter of

[1] Dr. Shirrell is a urologist practicing at Urology of Indiana. He is board certified by the American Board of Urology.

[2] Dr. Brewer is a gynecologist practicing at Rebecca Brewer M.D., LLC. She is board certified by the American Board of Obstetrics and Gynecology.

[3] Dr. Antolin is a gynecologist practicing at Henry County Medical Group in New Castle, Indiana. He is board certified by the American Board of Obstetrics and Gynecology.

[4] Dr. Maes is a gynecologist practicing at Fairhaven Obstetrics & Gynecology in Goshen, Indiana. He is board certified by the American Board of Obstetrics and Gynecology.

law. Under Indiana law, Bard's motion for partial summary judgment should be granted on the following claims for the following plaintiffs:

- **Plaintiff McCloskey:** Bard is entitled to summary judgment on **all claims** (Counts I-VII) pursuant to the Indiana Statute of Limitations because Plaintiff failed to file her complaint within the applicable two-year statute of limitations. Summary judgment should also be granted as to her claims of **Negligence** (Count I); **Strict Liability Design Defect** (Count II); **Strict Liability Manufacturing Defect** (Count III); and **Strict Liability Failure to Warn** (Count IV) due to failure to establish proximate causation and because she has not alleged a manufacturing defect. Dr. Shirrell was unequivocal that he still would recommend Align to Mrs. McCloskey today if she reported as a new patient with the same symptoms: "Based on her findings at the time of presentation, I would still recommend to her a midurethral sling." Deposition of William Shirrell, MD., 9/22/14 ("Shirrell Dep."), (attached hereto as McCloskey Exhibit 2) at 41:3-22. Finally, her **Breach of Express Warranty** (Count V) and **Breach of Implied Warranty** (Count VI) claims fail because these claims are subsumed by Indiana law and no warranties were made by Bard in this case.

- **Plaintiff Porter:** Bard is entitled to summary judgment on **all claims** (Counts I-VII) pursuant to Indiana's statute of limitations because Plaintiff failed to file her complaint within the applicable two-year statute of limitations. Summary judgment should also be granted on her claims of **Negligence** (Count I); **Strict Liability Design Defect** (Count II); **Strict Liability Manufacturing Defect** (Count III); and **Strict Liability Failure to Warn** (Count IV) because she cannot establish proximate causation and because she has not alleged a manufacturing defect. Dr. Brewer was unequivocal that she would still recommend the Align for Mrs. Porter if she came to her as a new patient with the same symptoms. *See* Deposition of

Rebecca Brewer, MD., 10/21/14 ("Brewer Dep."), (attached hereto as Porter Exhibit 2) at 43:13-24. Finally, her **Breach of Express Warranty** (Count V) and **Breach of Implied Warranty** (Count VI) claims fail because they are subsumed by Indiana law and no warranties were made in her case.

- **Plaintiff Prater:** Bard is entitled to summary judgment on Plaintiff's claims of **Negligence** (Count I); **Strict Liability Design Defect** (Count II); **Strict Liability Manufacturing Defect** (Count III); and **Strict Liability Failure to Warn** (Count IV) because she cannot establish proximate causation and because she has not alleged a manufacturing defect. Dr. Antolin was unequivocal that he would still recommend the Align to Ms. Prater today if she came to him as a new patient with the same symptoms. *See* Deposition of Romel Antolin, MD., 8/13/14 ("Antolin Dep."), (attached hereto as Prater Exhibit 2) at 82:13-83:14. In addition, her claims of **Breach of Express Warranty** (Count V) and **Breach of Implied Warranty** (Count VI) fail because they are subsumed by Indiana law and no warranty was made in her case.

- **Plaintiff Richards**: Bard is entitled to summary judgment on all claims (Counts I-VI and VII) pursuant to Indiana's **Statute of Limitations** because Plaintiff failed to file her complaint within the applicable two-year statute of limitations. Bard is also entitled to summary judgment on her claims of **Negligence** (Count I); **Strict Liability Design Defect** (Count II); **Strict Liability Manufacturing Defect** (Count III); and **Strict Liability Failure to Warn** (Count IV) because she cannot establish proximate causation and because she has not alleged a manufacturing defect. Dr. Maes was unequivocal that he would still recommend the Align to Ms. Richards today if she came to him as a new patient with the same symptoms. *See* Deposition of Vernon Maes, MD., 9/11/14 ("Maes Dep."), (attached hereto as Richards Exhibit 2) at 63:21-64:4. Finally, her claims of **Breach of Express Warranty** (Count V); **Breach of**

Implied Warranty (Count VI) fail because they are subsumed by Indiana law and no warranty was made in her case.

CHOICE OF LAW

A. Indiana Law Applies to the Indiana Plaintiffs

Indiana law applies to the plaintiffs named herein. When an action is transferred from one federal court to another, whether for convenience pursuant to 28 U.S.C. § 1404(a) or by the Judicial Panel on Multidistrict Litigation pursuant to 28 U.S.C. § 1407, "the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." In actions ***such as those of all Indiana plaintiffs***, which were ***filed directly in the MDL***, this Court has applied the choice of law rules of the "originating jurisdiction," defined as the state in which the plaintiff was implanted with the product. *Sanchez v. Boston Scientific Corp*., No. 2:12-CV-05762, 2014 WL 202787, at *4 (S.D. W.Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."); *see also In re Watson Fentanyl Patch Prods. Liab. Litig*., MDL No. 2732, 2013 WL 4564927, at *2 (N.D. Ill. Aug. 27, 2013) ("Indeed, the prevailing rule in this situation is that in a case that was directly filed in the MDL transferee court but that originated elsewhere, the law (including the choice of law rules) that applies is the law of the state where the case originated."). "Therefore, this Court should apply the choice of law rules of the state in which each plaintiff was implanted with the product.)."

All of the Indiana plaintiffs were implanted with Align in Indiana. Therefore, Indiana's choice of law rules apply to these Indiana plaintiffs.

B. Indiana Choice of Law Rules Require the Application of Indiana Substantive Law In These Cases

Indiana bears the most significant connection to each plaintiff's claims. No other state plausibly bears more significant contacts. Therefore, this Court should apply Indiana's substantive law to Plaintiffs' claims.

Indiana uses a modified *lex loci delicti* rule. *Thornton v. Sea Quest, Inc.*, 999 F. Supp. 1219, 1225 (March 19, 1998). The Indiana Supreme Court has provided that:

> In a large number of cases, the place of the tort will be significant and the place with the most contacts. In such cases, the traditional rule serves well. A court should be allowed to evaluate other factors when the place of the tort is an insignificant contact. In those instances where the place of the tort bears little connection to the legal action, this Court will permit the consideration of other factors such as: 1) the place where the conduct causing the injury occurred; 2) the residence or place of business of the parties; 3) the place where the relationship is centered. These factors should be evaluated according to their relative importance to the particular issues being litigated.

Hubbard Mfg. v. Greeson, 515 N.E. 2d 1071, 1073-74 (Ind. 1987) (citations omitted).

This court must first consider whether the place of the tort "bears little connection" to the legal actions of the Indiana plaintiffs. *Id.* The opposite is true. All of the Indiana plaintiffs were implanted with the Align in the state of Indiana by Indiana doctors, and all presently reside in Indiana. The place of the tort for each Indiana plaintiff is therefore Indiana and Indiana bears the most significant connection to each plaintiff's claims. No other state plausibly bears more significant contacts. Therefore, this Court should apply Indiana law to Plaintiffs' claims.

SUMMARY JUDGMENT STANDARD

To obtain summary judgment, Bard must demonstrate an absence of disputed issues of material facts such that Bard is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Summary judgment is warranted if Plaintiffs cannot make a showing sufficient to establish each element for which Plaintiffs bear the burden of proof. *Celotex Corp. v. Catreet*, 477 U.S. 317, (1996). Although the court will view facts and inferences in the light most favorable to Plaintiffs, *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 106 S.Ct. 1348, 89 L.E.d3d 538 (1986), Plaintiffs must nonetheless offer some "concrete evidence from which a reasonable juror could return a verdict in [their] favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 243, 256 (1986). Concrete evidence requires more than a mere "scintilla" of evidence, *id.* at 252, and Plaintiffs cannot avoid summary judgment simply by introducing conclusory allegations or speculation. *See, e.g., In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 837 (S.D. W.Va. 2011) (granting summary judgment because "there is completely lacking a cogent argument or genuine issue of material fact on the questions of defect and its cause of resulting harm").

GENERAL ARGUMENT & AUTHORITIES

I. STATUTE OF LIMITATIONS

Indiana's general statute of limitations for personal injury is ***two years*** "after the cause of action accrues." Ind. Code. § 34-11-2-4.

The statute of limitations accrues on "the date the plaintiff knew or should have discovered that she suffered an injury or impingement, and that it was caused by the product or act of another." *Degussa Corp. v. Mullens*, 744 N.E. 2d 407, 410 (Ind. 2001) (quoting *Barnes v.*

A.H. Robins Co., 476 N.E. 2d 84, 87-88 (Ind. 1985)). "It is not necessary for accrual that 'the full extent of the damage be known or even ascertainable but only that some ascertainable damage has occurred." *Del Vecchio v. Conseco, Inc.*, 788 N.E. 2d 446, 449 (Ind. App. 2003); *Kazmer v. Bayer Healthcare Pharmaceuticals, Inc.*, 2007 WL 4148003, at *2. "Events short of a diagnosis can provide a plaintiff with enough evidence to take action and once a plaintiff's doctor expressly informs the plaintiff that there is a reasonable possibility, if not probability, that an injury was caused by an act or product, then the statute of limitations begins to run." *See e.g. Morgan v. Columbus McKinnon Corp.*, 837 N.E. 2d 546 (Ind. App. 2006).

Indiana does not permit Plaintiffs to "effectively double the time in which they can bring any claim by 'failure to investigate suspicions that could easily have been confirmed.'" *Id.* at 550.

II. THE INDIANA PRODUCT LIABILITY ACT

All product liability claims under Indiana law are governed by the Indiana Product Liability Act ("IPLA"). Ind. Code § 34-20-1-1. Although Plaintiffs do not identify the IPLA in their Complaint, their claims will be discussed herein in the context of the IPLA. The IPLA governs all actions by a user or consumer against a manufacturer or seller for physical harm caused by a product, regardless of the legal theory upon which the action is brought. *Piltch v. Ford Motor Co.*, 11 F. Supp. 3d 884, 888 (7th Cir. 2014) (citing Ind. Code § 34-20-2-2).

The IPLA "imposes liability upon sellers of a product in a defective condition unreasonably dangerous to any user or consumer." *Ford Motor Co. v. Rushford*, 868 N.E. 2d 806, 809 (Ind. 2007), *see also* Ind. Code § 34-20-2-1. A plaintiff bringing an action under the IPLA must establish that: (1) the product was in a defective condition; (2) the product was

unreasonably dangerous; (3) the plaintiff was a foreseeable user or consumer; (4) the defendant was in the business of selling the product; (5) the product was expected to and did reach the user or consumer without substantial alteration; and (6) the defect in the product caused the plaintiff's injury. Ind. Code § 34-20-2-1; *Courne v. Marty Gilman, Inc.*, 452 F.3d 632, 635-36 (7th Cir. 2006); *Koske v. Townsend Eng'g Co.*, 551 N.E. 2d 437, 440-41 (Ind. 1990).

A product can be defective because of a manufacturing defect, a design defect, or a lack of adequate instructions or warnings. Ind. Code § 34-20-2-1 through -3; *Hoffman v. E.W. Bliss Co.*, 448 N.E. 2d 277, 281 (Ind. 1983). Inadequate warning and defective-design claims sound in negligence, regardless of how they are styled. *Piltch*, 11 F. Supp. at 888. "To prevail on a negligence claim a plaintiff must establish: (1) a duty owed by the defendant to the plaintiff; (2) a breach of that duty by the defendant; and (3) an injury to the plaintiff proximately caused by the breach." *Rushford*, 868 N.E. 2d at 810.

"A product contains a manufacturing defect when it deviates from its intended design." *Westchester Fire Ins. Co. v. Am. Wood Fibers, Inc.*, 2006 WL 3147710, at *5 (N.D. Ind. Oct. 31, 2006). The theory applies where the product has a defect that "is the result of a problem in the manufacturing process." Joseph R. Alberts, Robert B. Thornburg & Hilary G. Buttrick, *Survey of Recent Developments in Indiana Product Liability Law*, 45 Ind. L. Rev. 1279, 1285 (2012).

A. Warning Causation Is Required Under Indiana Law

i. Indiana Applies The Learned Intermediary Doctrine

Indiana courts have repeatedly recognized the learned intermediary doctrine, as have federal courts applying Indiana law. *See e.g.*, *Allberry v. Parkmor Drug, Inc.*, 834 N.E. 2d 199, 203 n.4 (Ind. App. 2005); *Phelps*, 836 F.2d at 301-03 (applying Indiana law); *Parks v. Danek Medical*, 1999 WL 1129706, at *6 (N.D. Ind. June 17, 1999) (applying Indiana law). *Accord*

Hooks v. SuperX, Inc. v. McLaughlin, 642 N.E. 2d 514, 518 (Ind. 1994) ("[W]e agree that the responsibility of warning patients about drug side effects lies with physicians.").

The learned intermediary doctrine provides that "a prescription drug manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer." *Allberry*, 834 N.E. 2d at 203 n. 4. "By adequately warning the doctor, the manufacturer fulfills its duty and avoids any liability for failure to warn." *Phelps*, 836 F.2d at 299 (applying Indiana law).

Under the doctrine, where the prescribing physician is properly warned, a manufacturer has no further duty to warn "down-line" health care workers, or ultimate users. *See id.* at 301-03 (stating that where the physician is properly warned, the manufacturer has no duty to warn down-line healthcare workers, such as nurses); *Parks*, 1999 WL 1129706, at *6 (stating that "even where the warning to the physician may be inadequate, the learned intermediary rule is not suspended and a duty to warn the patient imposed.").

ii. Proximate Causation and Cause-in Fact Are Required

Indiana requires proof of proximate causation in any failure to warn case irrespective of the learned intermediary doctrine. *Rushford*, 868 N.E. 2d at 810. Thus, a physician's prior user knowledge of the risks can defeat warning causation. *See Phelps*, 836 F.2d 296 at 304 (manufacturer "did not have to warn [the prescriber] of those dangers which he already knew") (applying Indiana law); *Minisan v. Danek Medical, Inc.*, 79 F.Supp. 2d 970, 978 (N.D. Ind. 1999) ("[E]ven if the manufacturer provides inadequate information, however, the manufacturer will not be liable if the plaintiff's physician independently knew of the risks and failed to advise the plaintiff.") (applying Indiana law); *York v. Union Carbide Corp.*, 586 N.E. 2d 861, 871 (Ind. App. 1992) (manufacturer need not give warning that "would merely confirm something already

known to [the user's] personnel"). Similarly, a physician's taking a risk into account and deciding to prescribe despite that risk also defeats warning causation. *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003) (affirming summary judgment where prescriber "took the risks that [plaintiff] would develop adverse side effects into account when prescribing") (applying Indiana law)).

B. Breach of Express and Implied Warranty Are Subsumed By Indiana Law

A number of Indiana courts have recognized that "tort-based breach-of-warranty claims have been subsumed into the PLA." [5] So have a number of federal courts, including the Seventh Circuit. *Piltch*, 11 F.Supp. 3d 884, 888; *see also Hathaway v. Cintas Corporate Services, Inc*., 903 F.Supp 2d 669 (N.D. Ind. 2012); *McGookin v. Guidant Corp*., 942 N.E. 2d 831 (Ind. App. 2011). This Court has also previously recognized that the learned intermediary doctrine requires the dismissal of Plaintiffs' express warranty claims when they "are simply repackaged as failure to warn claims."[6]

Regardless, warranty claims under Indiana law require the existence of a warranty and proof of proximate causation. *Ortho Pharmaceutical Corp*, 388 N.E. 2d at 551.

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[5] *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc*., 2006 WL 299064, at *3 (N.D. Ind. Feb. 7, 2006); *N.H. Ins. Co. v. Farmer Boy AG, Inc*., 2000 WL 33125128 at *3 (S.D. Ind. Dec. 19, 2000); *Condon v. Carl J. Reinke & Sons, Inc*., 575 N.E. 2d 17, 18 (Ind. Ct. App. 1991); *McGookin v. Guidant Corp*., 942 N.E. 2d 831 (Ind. App. 2011). *Cf. Kovach v. Caligor Midwest*, 913 N.E. 2d 193, 197 (Ind. 2009) (avoiding the issue of whether warranty claims are subsumed by the PLA but noting that several Indiana courts and federal courts applying Indiana law have concluded that they are subsumed).

[6] "Here, the plaintiffs' fraud-based claims and warranty claims are simply repackaged failure-to-warn claims . . . If the learned intermediary doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action . . . then the doctrine would be rendered meaningless." *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6886129, at *5 (S.D.W. Va. Nov. 24, 2014) (internal quotations omitted). Indiana Courts recognize the learned intermediary doctrine. *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E. 2d 541, 549 (Ind. App. 1979). Therefore, summary judgment should be granted on Plaintiffs' express and implied warranty claims on this basis as well.

ARGUMENTS APPLICABLE TO ALL INDIANA PLAINTIFFS

A. Summary Judgment Should Be Granted on Plaintiffs' Manufacturing Defect Claims

None of the Indiana plaintiffs has alleged that her Align made a deviation from the intended design of the product or otherwise had a manufacturing defect. Therefore, summary judgment is warranted on manufacturing defect claims as to the Plaintiffs.

No Indiana plaintiff's expert has set forth evidence to support the allegation that her Align had a manufacturing defect. Similarly, no Indiana plaintiff has adduced any evidence of any difference between her Align and Bard's plans and specifications for the product. Therefore, summary judgment should be granted on Plaintiffs' manufacturing defect claims.

While Plaintiffs bear the burden of proving a manufacturing defect, Bard has also presented evidence that the Align systems received by these plaintiffs were in fact manufactured in accordance with Bard's specifications. Dr. Maureen Reitman, Bard's biomedical, biomaterials, and polymer science expert witness in Wave 1 and 2 cases has reviewed the lot traceability documentation for each of the Plaintiffs at issue in this motion and based on that review, has determined that each of the products implanted in the Plaintiffs met all manufacturing specifications. *See* Expert Report of Dr. Maureen Reitman, pg. 69-70, attached hereto as All Plaintiffs Exhibit 1[7]. Therefore, Bard is entitled to summary judgment on the manufacturing defect claims of all Indiana plaintiffs addressed in this motion.

B. Summary Judgment Should Be Granted on Plaintiffs' Negligent Inspecting, Marketing, Packaging and Selling Claims

In the Master Complaint, Case No. 2:10-MD-02187, plaintiffs contend Bard breached an alleged duty to Plaintiffs by "[f]ailing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm…" (MC Para. 64(d)). Plaintiffs further contend Bard

[7] A true and correct copy of this report is attached, respectively, to each Indiana Plaintiff's Motion as Exhibit 1.

breached alleged duties related to marketing, packaging, and/or selling. (MC Para. 64(e)). To the extent these claims are distinct from Plaintiffs' manufacturing, design and warning claims, the claims fail for lack of evidence.

To prevail on a negligence claim plaintiffs must establish (1) a duty owed by the defendant to the plaintiff; (2) a breach of that duty by the defendant; and (3) an injury to the plaintiff proximately caused by the breach. *Rushford*, 868 N.E. 2d at 810. Here, Plaintiffs have adduced no evidence in support of their claims for negligent inspection, marketing, packaging, and selling. None of Plaintiffs' experts have testified that Bard breached the applicable standard of care in the manner it inspected, marketed, packaged or sold plaintiffs' specific Align Systems. Even if such testimony were deemed to exist, there is no evidence, and none of Plaintiffs' expert witnesses have testified, that any such breach caused the alleged damages that are the subject of Plaintiffs' claims.

The Court should therefore grant summary judgment in Bard's favor on Plaintiffs' claims of negligent inspection, marketing, packaging, and selling.

PLAINTIFF-SPECIFIC ARGUMENTS & AUTHORITIES

I. PLAINTIFF VICKI MCCLOSKEY

A. Plaintiff's Claims are Barred Under The Two-Year Statute of Limitations

Dr. Shirrell implanted Mrs. McCloskey with an Align to treat her SUI on ***December 29, 2009***. Plaintiff did not file her Complaint until ***January 22, 2014, more than four years later***. Even under a generous reading of Indiana's accrual law, Plaintiff's claims were barred no later than December 2012 because she had an awareness of her alleged injuries and a reasonable suspicion–indeed, an actual belief–that they were caused by her Align mesh as of at least as early as December 2010. Plaintiff unequivocally testified at her deposition and swore in her Plaintiff

Fact Sheet that she attributed her pain, bleeding, recurrence, worsening incontinence and urinary problems to her mesh implant as of December 2010:

Q: I'd like you to look at paragraph D, please. Paragraph D says "To the best of your knowledge and recollection, please state approximately when you first saw a healthcare provider for each of those bodily injuries you claim to have experienced relating to the pelvic mesh product." Do you see that?
A. Yes, sir.
Q. And the first one says, "Pain, approximately December 2010."
A. Right.
Q. So you were attributing pain to the mesh as of December 2010?
A. Yes.
Q. The next one says, "dyspareunia," and again, you don't know what that means right?
A. No, I don't know what that means.
Q. The one after that says "bleeding," and that one says, "approximately December 2010."
A. Correct.
Q. Do you see that?
A. Yes.
Q. So you were attributing bleeding to the pelvic mesh at that time?
A. Yes.
Q. The next one says, "recurrence and worsening of incontinence," also December of 2010. You were attributing those symptoms to the mesh at that time?
A. Correct.
Q. And the last one says "urinary problems, approximately December 2010." Do you see that?
A. Yes.
Q. And you were attributing those problems to the mesh—
A. Yes.
Q. --at that time; right?
A. Yes, sir.

Deposition of Plaintiff Vickie McCloskey, 8/6/14 ("McCloskey Dep."), (attached hereto as McCloskey Exhibit 3) at 94:10-95:22.

Based on the plaintiff's own sworn testimony and Fact Sheet, Indiana's two-year statute of limitations began to run no later December 2010 and her claims expired by December 2012. Plaintiff did not file her Complaint until January 22, 2014, long after the statute had run. Accordingly, all of Mrs. McCloskey's claims should be dismissed because they are time-barred.

B. Plaintiff's Claims of Failure to Warn and Negligence Based on Inadequate Warnings Fail Because She Cannot Establish Proximate Causation

Plaintiff cannot establish warnings causation because (1) there is no evidence that Dr. William Shirrell would have acted differently in prescribing the Align based on different information in a way that would have prevented Mrs. McCloskey from receiving it.

Dr. Shirrell implanted the Align to treat Mrs. McCloskey's SUI on December 29, 2009. Shirrell Dep. at 18:24-19:2. Dr. Shirrell still uses the Align today. *Id.* at 17:1-2. He has used polypropylene mesh slings to treat SUI about 750-1000 times in his career. *Id.* at 18:4-7. He used the Align in about a third of those cases, or between 250-330 times. *Id.* at 18:8-13. Dr. Shirrell has used these products, including the Align, because: "I would tell you that midurethral slings with polypropylene mesh is considered the standard of care for surgical repair." *Id.* at 20:12-21:4. His opinion has not changed since he implanted the Align in Mrs. McCloskey in 2009. *Id.* at 21:9-18. In fact, Dr. Shirrell currently gives his patients the January 3, 2014 AUGS/SUFU statement that unequivocally supports these products as the gold standard treatment for SUI. *Id.* at 34:17-41:2; Dep. Ex. 4 (attached hereto as McCloskey Exhibit 4). He does so in direct response to the TV advertisements from plaintiffs' lawyers because of the "misinformation and anxiety" they spread. *Id.* at 35:13-20.

Dr. Shirrell was unequivocal about what he would have recommended to Mrs. McCloskey today if she came to him as a new patient with the same symptoms: "Based on her

findings at the time of presentation, I would still recommend to her a midurethral sling." *Id.* at 41:3-13.

> Q: And would you recommend the Align sling?
> A: I have no hesitation recommending that sling to her. Again, it oftentimes boils down to the contracted arrangement between the facility and, you know, the site where we're going to be doing the procedure.
> Q: If the Align sling was available, would you use it?
> A: I would have no qualms using it.

Id. at 41:14-22.

Dr. Shirrell has no reason to believe that the Align is defective. *Id.* at 21:19-22:1 ("Clinically, I would tell you I think it's a fine sling.") and 23:16-24 ("I think clinically it's a very good procedure. It makes patients happy."). Dr. Shirrell also testified that he has not changed his discussion of the risks associated with Align that he has with patients since 2009. *Id.* at 62:19-21. He also testified that at the time of Mrs. McCloskey's implant, he was aware of the very risks that Mrs. McCloskey alleges, including pain, bleeding, infection, urinary retention, erosion, dyspareunia. *Id.* at 60:17-62:18.

There is no evidence at all that Dr. Shirrell would have made a different prescribing decision for Mrs. McCloskey based on different information. Plaintiffs only asked him a few questions at his deposition, none addressed his prescribing decision for Mrs. McCloskey, and Dr. Shirrell ended his deposition by reaffirming his testimony that the Align is safe and effective based on his experience implanting it hundreds of times. *Id.* at 138:2-7. Accordingly, Bard is entitled to summary judgment on Plaintiff's claims based on an alleged inadequate warning.

C. Plaintiff's Express and Implied Warranty Claims Should be Dismissed

Mrs. McCloskey's express and implied warranty claims must fail as they are subsumed by the IPLA. Regardless, both claims would fail because (i) there is no evidence that the Plaintiff saw or relied on any alleged express or implied warranty from Bard prior to her implant

procedure, and (ii) those claims fail pursuant to the learned intermediary doctrine and lack of proximate causation for the reasons explained above.

Mrs. McCloskey testified at her deposition that she does not know the name of the product that was implanted in her. McCloskey Dep. at 235:20-23. She has never attempted to communicate with Bard for any reason, *id.* at 20:3-5 and she had not researched the Align product prior to her implant. *Id.* at 89:13-16. In fact, Mrs. McCloskey testified that she had not heard of C.R. Bard even as of the date she filed her lawsuit:

> Q. Prior to the time you filed your lawsuit, had you ever heard of C.R. Bard?
> A. No.
> Q. Do you know anyone who works at Bard?
> A. No.
> Q. You've never spoken with anyone employed at Bard, right?
> A. No.

Id. at 300:1-9.

There is therefore no evidence Mrs. McCloskey saw, heard or relied on any type of warranty or representation from Bard regarding the Align.[8] Accordingly, Bard is entitled to summary judgment on plaintiff's express and implied warranty claims.

II. PLAINTIFF CHRISTINA PORTER

A. Plaintiff's Claims are Barred Under The Two-Year Statute of Limitations

Dr. Brewer implanted Ms. Porter with an Align to treat her SUI on ***February 24, 2009***. Plaintiff did not file her Complaint until ***December 26, 2013***, ***more than four years later***. Even under a generous reading of Indiana's accrual law, Plaintiff's claims were barred no later than April 2011, because she had an awareness of her alleged injuries as of at least two weeks after

[8] In fact, in consenting to the implant Mrs. McCloskey admitted "that no guarantee or assurance has been made as to the results that may be obtained" following the surgery. *See* McCloskey's implant consent form, attached hereto as McCloskey Exhibit 5.

her implant procedure. Plaintiff unequivocally testified at her deposition that she began to experience worsening urinary problems two weeks after her implant:

> A. Yes, because whenever I first start having problems is two weeks after my surgery, and that's when I noticed there's something going on with my bladder. And the symptoms kept building and building and building. And I just kept getting more and more symptoms.
> Q. So two weeks after your surgery you started noticing problems with your bladder, correct?
> A. Yes.

Deposition of Plaintiff Christina Porter, 7/1/14 ("Porter Dep.") (attached hereto as Porter Exhibit 3) at 81:18-82:1.

Ms. Porter testified further that six weeks after her implant, she began to experience pain with intercourse. *Id.* at 83:13-84:9. Despite noticing her medical condition had changed, plaintiff never returned to Dr. Brewer, or attempted to see any other doctor in order to appreciate and treat the cause of her alleged injuries. *Id.* at 82:2-20.

Indiana law is clear that Ms. Porter is not permitted to "effectively double the time in which [she] can bring any claim by failure to investigate suspicions that could easily have been confirmed." Ms. Porter testified in her deposition that she was not even aware she had a mesh implant until the day before her deposition. *Id.* at 73.[9] Indiana law does not allow Ms. Porter to extend her accrual date because of her own failure to seek a diagnosis. Rather than seeking prompt treatment in March or April of 2009, she did not undertake any investigation of her symptoms and did not file her complaint until December 26, 2013, long after the statute had run. Accordingly, all of Ms. Porter's complaints should be dismissed because they are time-barred.

[9] Plaintiff was in fact on notice that she was having a sling placed, because it said so on her consent forms, attached hereto as Porter Exhibit 4 (PORTERC_BLOOH_MDR00824-825).

B. Plaintiff's Claims of Failure to Warn and Negligence Based on Inadequate Warnings Fail Because She Cannot Establish Proximate Causation

Plaintiff cannot establish warnings causation because there is no evidence that Dr. Brewer would have acted differently in prescribing Align based on different information in a way that would have prevented Ms. Porter from receiving it.

Dr. Rebecca Brewer implanted the Align to treat Mrs. Porter's SUI on February 24, 2009. Brewer Dep. at 101:18-22. She still uses the Align today. *Id.* at 16:18-17:1, 18:4-6.

Dr. Brewer has used a polypropylene mesh sling to treat SUI several hundred times in her career. *Id.* at 27:21-25. She has used the Align more than 20 times in 2013-2014. *Id.* at 26:9-27:1. Each time she implanted an Align, or any polypropylene mesh sling, she did so because she believed that its benefits outweighed its risks for her patient. *Id.* at 28:22-29:7. The same was true for Mrs. Porter. *Id.* at 29:8-11. Dr. Brewer believes that mesh mid-urethral slings are the standard of care for SUI, that they are safe and effective, and that they improve the quality of life for her patients. *Id.* at 31:20-32-17; 35:17-25; 38:2-6. She has no reason to believe that the Align is a defective product. *Id.* at 29:12-14. As of the date of her deposition, she had at least one Align surgery scheduled. *Id.* at 29:15-22.

Dr. Porter was unequivocal about what she would have recommended to Mrs. Porter today if she came to her as a new patient with the same symptoms:

> Q: When you reviewed Ms. Porter's medical records in preparation for your deposition today, did you review her condition prior to having the surgery?
> A: I reviewed her history.
> Q: Okay. Did you review her symptomology relating to her stress urinary incontinence?
> A: Yes.
> Q: And if Ms. Porter were to come to you today as a new patient and presented with the same symptomology that she presented to you back in 2009, would you still recommend the Align product for her?
> A: I would.

Id. at 43:13-24. There is no evidence that Dr. Brewer would have made a different prescribing decision for Mrs. Porter. Following Plaintiff's questioning, Dr. Brewer confirmed Plaintiff's lawyer had not shown her any scientific information indicating the product is not safe and effective and that she intended to proceed with her scheduled Align procedures. *Id.* at 145:22-146:1, 150:7-10, 154:22-24. Accordingly, Bard is entitled to summary judgment on Plaintiff's claims based on an alleged inadequate warning.

C. Plaintiff's Breach of Express and Implied Warranty Claims Should be Dismissed

Ms. Porter's express and implied warranty claims must fail as they are subsumed by the IPLA. Regardless, both claims would fail because (i) there is no evidence that the Plaintiff saw or relied on any alleged express or implied warranty from Bard prior to her implant procedure, and (ii) those claims fail pursuant to the learned intermediary doctrine for reasons explained above.

Ms. Porter testified at her deposition that she did not even know the name of the product that was implanted in her until the day before her deposition:

> Q. Do you know the name of the product that was implanted in you?
> A. I just learned about it yesterday.
> Q. Okay. And what is your understanding is the name of the product?
> A. All I know is it's called Bard. That's it.

Porter Dep. at 20:11-16. The Plaintiff testified that she has never attempted to contact Bard for any reason. *Id.* at 20:20-22. She testified she did not really understand what Bard is:

> Q. Do you understand who it is you sued?
> A. No. I do not know who. I just know it's Bard. That's all I know. I don't know where their company is out of, the manufacturer, or what they do, nothing. That's all I know is the name.

Id. at 74:1-5. She has never spoken to or known anyone at Bard and stated that the only source of information she had on Bard was her lawyers. *Id.* at 214:7-8; 11-13; 104:8-12.

Finally, she admitted that no one made any guarantees about the procedure regarding the outcome of the Align procedure:

> Q. Were any guarantees made to you?
> A. No.
> Q. Did you ever assume there were any guarantees in the surgery?
> A. No.

Id. at 222:2-6.[10]

Accordingly, Bard is entitled to summary judgment on plaintiff's express and implied warranty claims.

III. PLAINTIFF LINDA PRATER

A. Plaintiff's Claims of Failure to Warn and Negligence Based on Inadequate Warnings Fail Because She Cannot Establish Proximate Causation

Plaintiff cannot establish warnings causation because there is no evidence that Dr. Antolin would have acted differently in prescribing the Align based on different information in a way that would have prevented Ms. Prater from receiving it.

Dr. Romel Antolin implanted the Align to treat Ms. Prater's SUI on March 10, 2010. Antolin Dep. at 79:25-80:3. He still offers the Align polypropylene mesh slings to treat SUI today. *Id.* at 22:20-23:7, 114:20-23.[11]

Dr. Antolin has been using polypropylene mesh slings to treat SUI for fifteen years. *Id.* at 24:11-15. He estimates that he has implanted 80-100 mesh slings in his career and that he has

[10] *See also* Porter Exhibit 4 attached hereto (plaintiff's signed consent to implant procedure, indicating that "I hereby state that no guarantee or assurances have been made to me concerning the results of the authorized procedure.)".

[11] Dr. Antolin has not performed a mesh implant surgery in the last year because there is a "new urologist in town." *Id.* at 23:8014. He does not refer patients to the urologist and would do a mesh sling surgery himself if a patient presented to him with SUI. *Id.* at 115:14-19.

used the Align slings exclusively over the last 7-8 years. *Id.* at 24:16-25-4, 114:20-23. Each time he has done so, including with Ms. Prater, he believed that the benefits of the product outweighed its risks for his patient. *Id.* at 25:5-17. His opinion has not changed today – he still believes the products are safe and effective and that their benefits outweigh their risks. *Id.* at 25:5-21. He further believes that they are the standard of care for SUI and that they improve the quality of life for his patients. *Id.* at 35:6-36:4. He agreed that the overwhelming majority of his patients have had a good experience with their mesh sling. *Id.* at 37:13-17. Dr. Antolin's support for these products was unequivocal:

Q: Okay. I'd like you to look at No. 3 in bold there. It says, 'Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.' Do you see that?
A: Yes.
Q: Do you agree with that statement also?
A: Yes.
Q: Why do you consider the polypropylene mesh sling for SUI to be a great advance in the treatment of SUI?
A: The success rates. From five years of success rates on them have been very good through the years. And, you know, my success with it in the past, ***I've been very happy with it.***
Q: Your patients have been happy with it also?
A: Yes. Yes.

Id. at 41:25-42:17.

Dr. Antolin was also unequivocal about what he would have recommended to Ms. Prater today if she came to him as a new patient with the same symptoms:

Q: Dr. Antolin, if Ms. Prater came to you today with the same symptoms that she was experiencing in 2010 when she had her surgery, would you recommend the same treatment for her?
A: ***Yes***.
Q: …If Ms. Prater were to come to you as a new patient today and tell you that she had the same symptoms that she described back in 2010, would you recommend that she have a midurethral polypropylene sling implanted as the first surgery for her stress urinary incontinence?
A: ***Yes.*** We would also -- we're talking about the conservative options

also; right? It would all be outlined that way, and then in the end she would choose.

Q: In other words, from the first time that you met Ms. Prater and you discussed the conservative options until the time that you performed the surgery using the Bard polypropylene sling, you would expect to have the same type of course with her today as you did back in 2010; correct?

A ***Yes. Same conversation.***

Id. at 82:13-83:14.

There is no evidence that Dr. Antolin would have made a different prescribing decision for Ms. Prater -- ***he does not do any other type of surgery to treat SUI.*** *Id.* at 46:10-13. He has not done so for a decade or more because "the midurethеral sling has done the job…since the midurthreal slings have come, that's basically worked very, very well." *Id.* at 47:2-9. He would not have recommended any other type of surgery for her other than the use of a polypropylene mesh sling. *Id.* at 64:12-15. Further, his discussion about the risks of midurethral slings has not changed since he saw Ms. Prater in 2010. *Id.* at 62:16-19.

Plaintiff's effort to confuse Dr. Antolin at his deposition failed to change his opinions by the end of his deposition:

Q: And your current thinking is that the Align is an appropriate product; correct?

A: Yes.

Q: And your current thinking is that the Align's benefits outweigh its risks for patients like Ms. Prater; correct?

A: Yes.

Q: And you haven't heard anything at least today that would lead to you question that; correct?

A: Yes.

Id. at 203:19-204:5. Accordingly, any suggestion that Dr. Antolin would have reversed his decade-long decision-making in regards to Ms. Prater is utter speculation. Therefore, Plaintiff cannot establish warning causation under Indiana law and her warnings claims fail as a matter of law.

B. Plaintiff's Express and Implied Warranty Claims Should Be Dismissed

Ms. Prater's express and implied warranty claims must fail as they are subsumed by the IPLA. Regardless, both claims would fail because (i) there is no evidence that the Plaintiff saw or relied on any alleged express or implied warranty from Bard prior to her implant procedure, and (ii) those claims fail pursuant to the learned intermediary doctrine for reasons explained above.

Ms. Prater testified that she did not even know who the manufacturer of the Align was at the time of her implant:

> Q. Okay. And so it is your testimony that at the time you had the surgery, you didn't know the name of the product?
> A. No, sir.
> Q. And did you know the manufacturer of the product at that time?
> A. No, sir.

Deposition of Plaintiff Linda Prater, 7/25/14 ("Prater Dep.") (attached hereto as Prater Exhibit 3) at 27:16-22. Further, Ms. Prater testified that she had never communicated with Bard for any reason, *id.* at 65:19-21 and that she does not know anyone at Bard. *Id.* at 282:25-283:1. She also does not know, what, if anything Bard told Dr. Antolin prior to her implant. *Id.* at 283:15-17. She also repeatedly stated that no guarantees were made to her regarding the outcome of her Align procedure. *Id.* at 223:4-7; 232:2-12; 235:1-4; 273:14-22.[12] Accordingly, Bard is entitled to summary judgment on Plaintiff's express and implied warranty claims.

[12] This is also reflected in the Plaintiff's consent form to her implant procedure, which is attached hereto as Prater Exhibit 4 (stating that "I acknowledge that no guarantees have been made to me concerning the results of the operation, procedure or treatment…".).

IV. PLAINTIFF LINDA RICHARDS

A. Plaintiff's Claims Are Barred Under The Two-Year Statute of Limitations

Dr. Maes implanted Ms. Richards with an Align to treat her SUI on ***August 4, 2009***. Plaintiff did not file her Complaint until ***November 4, 2013, more than four years later***. Even under a generous reading of Indiana's accrual law, Plaintiff's claims were barred no later than October 4, 2011, because she stated in her verified Plaintiff Fact Sheet that she began to have problems two months following her surgery that related to mesh, although she has not had a chance to be seen by a physician for these problems.[13]

Ms. Richards was asked in her PFS "[w]hen is the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the pelvic mesh product(s)?". She responded "[a]bout 2 months after my initial surgery. I had heavy bleeding which scared me because I didn't know what was going on along with the heavy feeling." Richards PFS at 7. She was also asked "When did you first attribute these bodily injuries to the pelvic mesh product(s)?" and stated "I knew right away that these problems were due to the mesh. I had previously had a hysterectomy so I knew I couldn't be bleeding like it was from my period. The only thing that had changed in my body immediately prior to the bleeding was my mesh implant surgery." *Id.* Ms. Richards failed to seek medical attention that would have allowed her to determine the cause of these alleged injuries. She testified that she has not yet sought medical attention to address her symptoms as of July 10, 2014, the date of her deposition. Deposition of Plaintiff, Linda Richards ("Richards Dep.") (attached hereto as Richards Exhibit 4), 7/10/14 at 94:19-95:14.

Indiana law does not allow a plaintiff to effectively toll the statute of limitations because they have failed to investigate the cause of their alleged injuries in a way that allows them to

[13] *See* Linda Richards PFS at 7 (attached hereto as Richards Exhibit 3).

make the connection between a medical device and their injury. By the Plaintiff's own admission, she knew that she was experiencing symptoms related to the mesh two months after her August 4, 2009 implant procedure. Therefore, the statute of limitations had run, effective August 4, 2011. Because the plaintiff failed to file her Complaint in advance of that date, her claims must be dismissed as they are time-barred.

B. Plaintiff's Claims of Failure to Warn and Negligence Based on Inadequate Warnings Fail Because She Cannot Establish Proximate Causation

Plaintiff cannot establish warnings causation because there is no evidence that Dr. Maes would have acted differently in prescribing the Align based on different information in a way that would have prevented Ms. Richards from receiving it.

Dr. Maes implanted the Align to treat Ms. Richards' SUI on August 4, 2009. Plaintiff Fact Sheet at 5 (attached hereto as Richards Exhibit 5). Dr. Maes still uses the Align today. Maes Dep. at 23:21-25. He has used polypropylene mesh slings to treat SUI about 150-200 times in his career. *Id.* at 29:4-10. He used the Align in most of those cases after discovering he preferred it to TVT. *Id.* at 25:9-25; 29:1-16. Dr. Maes has used these products, including Align, because he believes polypropylene mesh products are the standard of care for vaginal treatment of SUI. *Id.* at 30:8-15. His opinion has not changed since he implanted the Align in Ms. Richards in 2009. *Id.* at 61:18-24.

Dr. Maes stated unequivocally that if Ms. Richards presented today with the same symptoms he would again treat her with the Align:

Q. As you sit here today, would you use the Align product on Ms. Richards again?
A. I use it on—yeah, yes.
Q. Would you have done anything differently as you sit here today?
A. No.
Q. Do you have plans to use Align in the future?
A. Yes.

Id. at 63:21-64:4; and 144:5-20 (Dr. Maes stating that being shown the Material Safety Data Sheet in this case does not change his opinion and he would not have done anything differently with respect to his use of Align on the Plaintiff).

Dr. Maes also testified that he was aware of the risks associated with the Align procedure on the date of the Plaintiff's implant and that there was no specific warning that could have been provided to him at that time that was specific to the risks and benefits of Align that would have changed his decision to treat her with Align. *Id.* at 60:14-17; 78:12-16.

There is no evidence – at all – that Dr. Maes would have made a different prescribing decision for Ms. Richards based on different information. In fact, he ended his deposition by reaffirming that nothing has changed his opinion on the safety of Align and that he would not have done anything differently with respect to his decision to use Align to treat the Plaintiff. Accordingly, Bard is entitled to summary judgment on Plaintiff's claims based on an alleged inadequate warning.

C. Plaintiff's Express and Implied Warranty Claims Should Be Dismissed

Ms. Richards' express and implied warranty claims must fail as they are subsumed by the IPLA. Regardless, both claims would fail because (i) there is no evidence that the Plaintiff saw or relied on any alleged express or implied warranty from Bard prior to her implant procedure,[14] and (ii) those claims fail pursuant to the learned intermediary doctrine and lack of proximate causation for reasons explained above.

By the plaintiff's own admission, she never received any written or verbal information concerning the Align. Richards Dep. at 246:19-247:13. She never did any independent research on C.R. Bard. *Id.* at 78:4-6. She also had never spoken to or emailed anyone at Bard about her

[14] In fact, Plaintiff acknowledged in her consent to the implant procedure that "no guarantee or assurance has been made as to the results of the procedure…". *See* Richards Consent Form, attached hereto as Richards Exhibit 6.

surgery or the Align. *Id.* at 83:22-25; 270:1-5. She stated that she only knows that Bard manufactured her vaginal sling because her attorney told her that. *Id.* at 244:23-245:11.

CONCLUSION

For all of the foregoing reasons, Bard respectfully requests that the Court grant summary judgment on the specific claims set forth above.

Dated: January 9, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2015, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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